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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,146

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Michael Mahoney

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EXAMINER

WAGGLE, JR, LARRY E

ART UNIT

PAPER NUMBER

3775

NOTIFICATION DATE

DELIVERY MODE

09/17/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,146	<b>Applicant(s)</b> MAHONEY ET AL.	
	<b>Examiner</b> Larry E. Waggle, Jr	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 12-13, 19, 22-23, 35-43, 50 and 59-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-18, 20-21, 24-34, 44-49 and 51-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 August 2006, 23 October 2007 and 27 January 2009</u>       | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention I, Species A, claims 1-34 and 44-58 in the reply filed on 09 June 2009 is acknowledged. Claims 35-43 and 59-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Further, claims 12-13, 19, 22-23 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. They are withdrawn due to the specification not disclosing the limitations of the "shim," the "overhanging tab," and "two distraction paddles" as part of the elected species. The breakdown of the claims deemed to correspond to the species listed in the "Requirement for Restriction/Election," mailed on 22 May 2009, was as thought best by the examiner. Per the restriction requirement, it is the duty of the applicant to specifically identify each claim readable on the elected species.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "angled guide feature" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figure 29 appears to have an extraneous reference number 74b. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date

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of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 30, as disclosed on page 12, line 15; 32, as disclosed on page 12, line 22; 50, as disclosed on page 13, line 13; 414, as disclosed on page 17, line 7; 505, as disclosed on page 17, line 12; 514, as disclosed on page 17, line 14; 614, as disclosed on page 17, line 29; 752, as disclosed on page 18, line 19; and 1211, as disclosed on page 20, line 25. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 9 – 112b, 118, 122a, 143 and 152; Figure 10 – 110, 112b, 122a, 143

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and 152; Figure 11 – 110, 112b, 122a, 143 and 152; Figure 12 – 241 and 243; Figure 13 – 222b, 241 and 242; Figure 14 – 314; Figure 15 – 314, 333c, 341 and 343; Figure 16 – 314, 333c, 341 and 343; Figure 17 – 314, 322a and 341; Figure 18 – 422, 441 and 442; Figure 19 – 422; Figure 20 – 422, 441, 442 and 443; Figure 21 – 522; Figure 22 – 522, 541, 542 and 543; Figure 23 – 522; Figure 24 – 641; Figure 25 – 641 and 643; Figure 26 – 641; Figure 27 – 712, 741 and 742; Figure 28 – 741 and 742; Figure 29 – 74b; Figure 34 – 942; Figure 35 – 942; Figure 36 – 1352; Figure 37 – 1041; Figure 39 – 1181a and 1181b; Figure 40 – 1246 and 1248; Figure 41 – 1246 and 1248; Figure 42 – 1311, 1341, 1342 and 1380; and Figure 43 – 1311, 1341, 1342, 1343 and 1380.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy

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must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 20-21, 25-28, 44, 46, 49, 52, 54-58** are rejected under 35

U.S.C. 102(b) as being anticipated by Dorchak et al. (US Publication 2001/0031968).

Dorchak et al. disclose a surgical instrument system comprising a distractor (10; Figures 1-4) (i.e. means for distracting adjacent vertebrae) including a shaft (41a) a paddle (12a), the paddle including a height ( $h_1$  or  $h_2$ ) when inserted and being located on a distal end of the shaft and having an inferior surface and a superior surface including a means for preventing migration of the distractor (28; knurled, roughened surface or teeth extending beyond the superior surface); a filler bar (41b) extending



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substantially along at least one side of the shaft and paddle and slidably engageable to and removable from the distractor; an articulating implant inserter (600; Figure 23) (i.e. means for inserting an implant) including a shaft (602) (i.e. means for rotating the implant) and an articulatable implant holding element (604) located on an angled (as shown in Figure 24) distal end of the shaft, the articulatable implant holding element being operable from a proximal portion of the shaft to releasably hold an implant; and an implant (200) having a connecting element (428) that cooperates with the articulatable implant holding element to allow articulation of the implant to a desired angle upon operation of the implant holding element, domed inferior and superior surfaces and a bullet-shaped leading end (204) (bullet-shaped in at least two planes), wherein when the filler bar is engaged to the distractor, the filler bar provides rigidity and torque strength so that the distractor can be inserted between adjacent vertebrae in a first orientation and rotated to distract the adjacent vertebrae (pages 4 and 5, paragraph 0068), the distractor paddle and shaft present guide surface (26) and an angled guide surface (surface of 16) integrated with a distal portion of the paddle and accessing the surgical site through a minimally invasive port (i.e. tubes or laparoscopic instruments (pages 8 and 9, paragraph 0104)).

With regard the statement of intended use and other functional statements, such as "configured to" and "for," they do not impose any structural limitations on the claims distinguishable over Dorchak et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the

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reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

**Claims 2-11, 14-18, 29-34 and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dorchak et al.* (US Publication 2001/0031968) in view of *Frey et al.* (US Publication 2004/0117020).

*Dorchak et al.* disclose the claimed invention except for the distractor paddle being rotated approximately 90 degrees to a distraction orientation presenting a second height dimension being greater than the first height dimension. In the embodiment of Figures 7-9, *Frey et al.* teach a distractor (10) comprising a shaft (12) and a paddle (20) that includes a first height dimension when inserted in an insertion orientation (Figure 7) and a second height dimension (greater than the first) when rotated approximately 90 degrees to a distraction orientation (Figure 9) (page 5, paragraphs 0083-0085). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of *Dorchak et al.* with the distractor comprising a shaft and a paddle that includes a first height dimension when inserted in an insertion orientation and a second height dimension (greater than the first) when rotated approximately 90 degrees to a distraction orientation in view of *Frey et al.* in order to distract to and maintain the disc space at a greater height.

Dorchak et al. in view of Frey et al disclose the claimed invention except for the filler bar being dimensioned so as not to extend beyond the superior and inferior surfaces of the paddle. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. in view of Frey et al. with the filler bar being dimensioned so as not to extend beyond the superior and inferior surfaces of the paddle in order to allow for smooth, uninhibited movement of the filler bar with respect to the distractor, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Dorchak et al. in view of Frey et al. disclose the claimed invention except for the angled guide feature being formed from a shape memory material. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. in view of Frey et al. with the angled guide feature being formed from a shape memory material in order for the angled guide to be capable of conforming to the shape of the item it's guiding at the same time retaining it's initial shape, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

**Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorchak et al. (US Publication 2001/0031968).

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Dorchak et al. disclose the claimed invention except for the angled guide feature being formed from a shape memory material. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. with the angled guide feature being formed from a shape memory material in order for the angled guide to be capable of conforming to the shape of the item it's guiding at the same time retaining it's initial shape, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

**Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorchak et al. (US Publication 2001/0031968) in view of Lin (US Publication 2003/0130667)

Dorchak et al disclose the claimed invention except for the implant connection element being internal to the implant. Lin teaches an implant (200) having an internal connecting element (216) (Figure 11). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. with the implant having an internal connecting element in view of Lin in order to insure a stable connection between the holding element and the connecting element.

**Claims 47 and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorchak et al. (US Publication 2001/0031968) in view of Magee et al. (US Patent 5957927).

Dorchak et al. disclose the claimed invention except for the articulatable implant holding element including two sliding elements having distal implant impaction faces,

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the implant holding element being operable from a proximal handle to provide relative sliding in a proximal-distal direction along the shaft to selectively articulate the implant to a desired angle, wherein the position of the handle acts as a visual indicator for an angle through which the implant has been rotated. Magee et al. teach a surgical instrument (10) including two sliding elements (20) having distal impaction faces (interacting with 42 and 44), the instrument being operable from a proximal handle (12) to provide relative sliding in a proximal-distal to selectively articulate a device (32) to a desired angle, wherein the position of the handle acts as a visual indicator for an angle through which the implant has been rotated (as shown in Figure 4) (Figures 1-4 and column 3, line 1 - column 4, line 42). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. with the surgical instrument including two sliding elements having distal impaction faces, the instrument being operable from a proximal handle to provide relative sliding in a proximal-distal to selectively articulate a device to a desired angle, wherein the position of the handle acts as a visual indicator for an angle through which the implant has been rotated in view of Magee et al. in order to adjust the angular movement of the implant.

**Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorchak et al. (US Publication 2001/0031968) in view of Trieu et al. (US Publication 2004/0117019).

Dorchak et al. disclose the claimed invention except for the means for inserting including a ratchet gun. Trieu et al. teach a means for inserting including a ratcheting

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handle (page 12, paragraphs 00206-00206). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Dorchak et al. with the means for inserting including a ratcheting handle in view of Trieu et al. in order to precisely control the advancement of the implant to the operative site.

### **35 U.S.C. 112 6th Paragraph**

The examiner acknowledges the applicant's intentions of invoking 35 U.S.C. 112 6th paragraph by using the term "means for" in claim 49.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is 571-270-7110. The examiner can normally be reached on Monday through Thursday, 6:30am to 5pm, EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Larry E Waggle, Jr/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
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